

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Oleg Illich Epstein
Title of Invention : A Product designed to potentiate the therapeutic effects and to enhance the action of medicinal preparations

Date Filed : March 31, 2006
Serial No. : 10/574,524
Examiner : MANOHAR, Manu M.
Art Unit : 4161
Confirmation No. :

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epstein (aka Epshtein). The company I lead, Materia Medica Holdings, successfully sells a number of products based on combination of homeopathic and modern pharmacology. I am the inventor of the '524 application.

2. I am a widely recognized scientist in the field of pharmacology and physiology. I authored over 100 articles in peer review journals. I am well skilled in the art of modern pharmacology.

3. I have been a practicing homeopath for over 20 years. I am well familiar with fundamental homeopathic literature. I am well skilled in the art of homeopathic medicine.

4. It is my understanding that US patent No. 5,629,286 to Brewitt was used by the United States Patent and Trademark Office to reject certain claims of the '524 application. I reviewed Brewitt. It is my understanding that the Examiner stated that Brewitt's teaching of mixture of homeopathic dilutions would provide a reason for one of

ordinary skill in the art to combine a therapeutic dose with a homeopathically activated form of the same substance.

5. As one skilled in the art of homeopathic medicine I am well aware that use of homeopathic dilutions is common in homeopathic medicine. Therefore, it is my opinion that Brewitt's use of mixture of dilutions is common knowledge for any homeopathic practitioner. Brewitt deals strictly with homeopathic technology and states that there are drawbacks of using allopathic medicine, for example harsh side effects and virus mutation (col. 3, lines 48-49, and col. 4, lines 46-63).

6. As one skilled in the art of homeopathy, I declare that Brewitt's use of mixture of homeopathic dilutions provides no information whatsoever with respect to use of non-homeopathic components in the field of homeopathic medicine. In my opinion, one skilled in the art of homeopathic medicine would not consider using standard pharmacology, leave alone combination of homeopathic dilutions with a therapeutic dose, in the practice of homeopathic medicine or in any application of homeopathic preparations.

7. Therefore, it is my opinion, as one skilled in the art of homeopathic medicine, that Brewitt did not provide one skilled in the art with any reason to modify a homeopathic dose (e.g., as disclosed in Brewitt) in the manner of the claimed invention.

8. As one skilled in the art of pharmacology, it is my opinion that one of ordinary skill in the art would not look to homeopathic as a source of solution for modern pharmacology problems related to therapeutic doses.

9. I discovered that when a therapeutic dose is combined with a homeopathic dose, the combination results in a potentiation of the pharmacological activity of the compound and/or reduction in the undesired side effects. Brewitt does not provide any reason for one skilled in the art of pharmacology to modify the therapeutic dose, particularly for the specific substances claimed in the '524 application.

10. Therefore, it is my opinion that Brewitt does not provide any reason for one of ordinary skill in the art of pharmacology to combine a therapeutic dose with a homeopathically activated form.

11. As shown in the specification of the '524 application, administration of a therapeutic dose of a pharmaceutical substance in combination with a homeopathic activated form of the same pharmaceutical substance is more potent than the pharmaceutical substance alone or homeopathically activated dilutions of the same active pharmaceutical substance.

12. Thus, it is my opinion that Brewitt does not provide one skilled in the art of homeopathic medicine with any expectation that using a therapeutic dose in combination with homeopathic dilution would be successful, let alone would lead to the results obtained in the combination recited in the claims.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

Dated: October 08, 2009

Dr. Oleg I. Epstein